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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 of 3

### Complete if Known

Application Number	09/757,688
Filing Date	January 11, 2001
First Named Inventor	HEIL, Wolfgang
Group Art Unit	1615
Examiner Name	L.S. CHANNAVAJJALA
Attorney Docket Number	PLOVIN-0002-A

### NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS); title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	1	Decision in EP Opposition of EP Patent No. 1214076	
	2	Contraception, 43(1). 1991. 23-33., Melis G B et al., "A Comparative Study on the Effects of a monophasic Pill containing Desogestrel plus 20 Mug Ethynylestradiol a triphasic combination containing Gestodene on coagulatory factors." [c.f. MEDLINE an = 91168564]	
	3	Genazzani, A.R., F. Petraglia and A. Volpe (Ed.), Progress in Gynecology and Obstetrics; Second European Winter Conference in Gynecology and Obstetrics, Madonna Di Campliglio, Italy, March 1989. XXVI+944P. Parthenon Publishing Group Carnforth, England; Bilotta P et al., "Multicenter Clinical Trial on the new oral contraceptive containing 20 Mug Ethynylestradiol."	
	4	van Keep et al., 1981, The Workshop moderators; reports presented at the 3rd International Congress on the menopause, held in Ostend, Belgium, in June 1981, under the auspices of the International Menopause Society, "The Controversial Climateric."	
	5	Deutsches Arzneibuch, 9. Ausgabe, Seite 105, 1986.	
	6	Guillebaud J., Br. J. Family Planning 12 (suppl), Seite 35-43, 1987, "The forgotten pill and the paramount importance of the pill free week."	
	7	Losert et al., Arzneimittelforschung 35(I), No. 2 (1985), "Progestogens with Antimineralocorticoid Activity."	
	8	Filshie at al., Contraception: Science and Practice, Butterworths, Seite 76-82, 1989, "Practical prescribing of the combined oral contraceptive pill."	
	9	Fioretti et al., Contraception, March 1987, Vol. 35, No. 3, "Clinical and metabolic study of a new pill containing 20 mcg Ethiny-estradiol plus 0.150 mg Desogestrel."	
	10	Peterson et al., American Journal of Obstetrics and Gynecology, Vol. 168, No. 1, Part 1, 1993, "Effects of monophasic low-dose oral contraceptives on fibrin formation and resolution in young women."	
	11	British Medical Journal, Vol. 290, Seite 1474-1475, 1985, "Missed pill – conception: fact or fiction?"	
	12	Spona et al., Contraception 54, 71-77, 1996, "Shorter pill-free interval in combined oral contraceptives decreases follicular development."	

Examiner Signature	Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Sheet 2 of 3

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Group Art Unit	1615
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	13	Drife J.O., Annual Progress in Reproductive Medicine, 1993, "Oral contraception for the over-40s."	
	14	Kuhl et al., Das Klimakterium, 1987, s. 128-134, "Endokrine Veränderungen."	
	15	Fitzgerald et al., Advances in Contraception 10, 5-18, 1994, "A comparison of the effects of two monophasic low dose oral contraceptives on the inhibition of ovulation."	
	16	Endrikat et al., Contraception 55, 131-137, 1997, "A twelve-month comparative clinical investigation of two low-dose oral contraceptives containing 20µg gestodene and 30µg ethinylestradiol/75µg gestodene, with respect to efficacy, cycle control, and tolerance."	
	17	Sullivan et al., Fertility and Sterility 72, 1, 115-120, 1999, "Effect of 21-day and 24-day oral contraceptive regimens containing gestodene (60µg) and ethiny estradiol (15µg) on ovarian activity."	
	18	Endrikat et al., Contraception 64, 2, 99-105, 2001, "Double-blind, multicenter comparison of efficacy, cycle-control, and tolerability of a 23-day versus a 21-day low-dose oral contraceptive regimen containing 20 µg ethinyl estradiol and 75µg gestodene."	
	19	Elomaa et al., Contraception 60, 275-279, 1999, "Ovulatory potential of preovulatory sized follicles during oral contraceptive treatment."	
	20	Krattenmacher et al., XVII Meeting I.S.G.S.H. 25-28/Nov/1995, page 55, "Effects of drospirenone on blood pressure and heart rate in rats measured by highly sensitive radio-telemetry."	
	21	European Journal of Contraception and Reproduction Health Care, 1999, 4 (Suppl. 2); 17-25, ycle control, safety and efficacy of a 24-day regimen of gestodene 60µg/ethinylestradiol 15µg and 21-day regimen of desogestrel 150µg/ethinyl-estradiol 20µg."	
	22	European Journal of Contraception and Reproduction Health Care, 1999, 4 (Suppl. 2); 9-15, "The safety and contraceptive efficacy of a 24-day low-dose oral contraceptive regimen containing gestodene 60µg and ethinylestradiol 15µg."	
	23	Pearlstein et al., submitted for publication, "Treatment of premenstrual dysphoric disorder with a new drospirenone – containing oral contraceptive formulation."	
	24	Leidenberger, Klinische Endokrinologie für Frauenärzte, Kapitel 8, pp. 123-140, 1998, "Drospirenone: pharmacology and pharmacokinetics of a unique progestogen."	
	25	Runnebaum et al., Gynecological Endocrinology and Reproductive Medicine, Vol. 1, Gynecological Endocrinology, pp. 455-468, 1997, "The Female Climacteric."	

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